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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,795	03/08/2004	Michael Kalafatis	27433/04016	7857
24024	7590	09/27/2005	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			MAYER, SUZANNE MARIE	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/795,795	KALAFATIS ET AL.	
	Examiner	Art Unit	
	Suzanne M. Mayer, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-35 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27 is/are rejected.
- 7) ☒ Claim(s) 28-35 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7-7-04</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Status of the Claims

1. Claims 1-26 were cancelled by Applicant in a preliminary amendment filed on March 8, 2004. New claims 27-35 were added which are commensurate in scope with cancelled claim 26. Thus, claims 27-35 are pending and under examination in the present application.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on July 7, 2004 has been considered by the examiner. See signed and attached PTO-1449.

Claim Objections

3. Claims 27, 31 and 34 are objected to because of the following informalities:
Each claim contains minor typographical errors.

Claim 27 recites a range "between 50 nM and 500 yM", where the concentration of 500 should be stated as "μM".

Claim 31 recites, "wherein the sequence of then peptide", where then should read as the.

Claim 34 recites, "The method of claim 271", however, the claim should be dependent upon claim 27.

Claims 27-31 use the sequence identifier SEQ ID NO., whereas the acceptable and preferred nomenclature is SEQ ID No..

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a method of treating human subjects with blood clotting disorders by administering to said subjects a pharmaceutical composition where the peptide comprises a peptide that is 3 to 10 amino acids in total length, and wherein said peptide also comprises a sequence between 3 and 10 amino acids which are identical to portions of the human blood clotting factor Va. However, the use of the open comprising language in reference to a peptide that is 10 amino acids is indefinite given that the sequence is limited to a maximum length of 10 amino acids to begin with. Thus the claim would be clearer, if for example, the said peptide also comprises a sequence between 3 and 9 amino acids, or consists of 10 amino acids, which are identical to portions of the human blood clotting factor Va.

6. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite because the claim is drawn to a method of treating human subjects with blood clotting disorders by administering to said subjects a pharmaceutical composition where the peptide comprises a peptide that is 3 to 10 amino acids in total length, and wherein said peptide also comprises a sequence between 3 and 10 amino acids which are identical to a sequence of consecutive amino acids found within amino acids 322 to 331 or 352 to 356 of human blood clotting factor Va (SEQ ID No: 1).

However, the way the in which the claim reads, one would expect that SEQ ID No: 1 is representative of the entire 726 amino acid human blood clotting factor Va protein, and thus one would be able to clearly identify amino acids 322-331 or 352-356. However, this is not the case since SEQ ID No: 1 is only 50 amino acids in total length and is representative of amino acids 307-356 of the human blood clotting factor Va protein. Furthermore, since the amino acids of SEQ ID No: 1 are labeled with numbers 1-50, it is impossible to tell which amino acids are representative of amino acids 322-331 or 352-356 from the full length protein when SEQ ID No: 1 is relied upon as a reference sequence.

Prior Art of Interest – Not Relied Upon

9. Duve et al. (*PNAS USA*, 1992, 89, 2326-2340) teach a seven amino acid peptide which has three consecutive amino acids (Asp-Asn-Phe) which are 100% identical to 353-355 of the human blood clotting factor Va (see p. 2329, Figure 3, #11).

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10. Saunders et al. (WO 95/00633) teach a seven amino acid peptide that has four consecutive amino acids (Asp-Asn-Phe-Ser) that are 100% identical to amino acids 353-356 of human blood clotting factor Va (see claim 4, p. 79).

11. Wang et al. (US 6,165,737) teach a nine amino acid peptide that has four consecutive amino acids (Trp-Glu-Tyr-Phe) that are 100% identical to amino acids 321-324 of human blood clotting factor Va (see colum 63, line 19, and also see columns 93-94, SEQ ID No: 19).

12. Massignani et al./Chiron SPA (GB9916529.2, July 1999) teach a seven amino acid peptide that has five consecutive amino acids (Ile-Ala-Ala-Glu-Glu) that are 100% identical to amino acids 326-330 of human blood clotting factor Va (see colum 63, line 19, and also see columns 93-94, SEQ ID No: 19).

Conclusion

13. Claim 27 is rejected. Claims 28-35 are objected to for minor informalities. They are also objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and once said informalities are corrected.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Collectively, the references of interest teach some of the claimed limitations of the peptides for claims 27 and 28, e.g., peptides that are between three and 10 amino acids in length that comprise sequences that have 3-5 consecutive amino acids that are identical to the amino acids found within amino acids 322-331 or 352-356

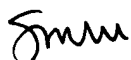
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of the human blood clotting factor Va. However, none of said references teach or suggest the use of these peptides in a method of administration to human subjects in order to treat blood clotting disorders.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

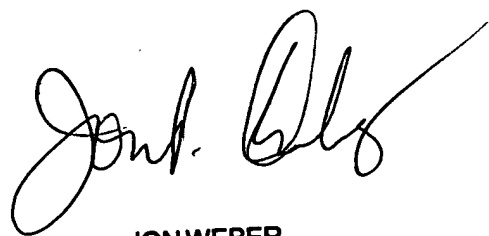
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SMM

17 September 2005



JON WEBER
SUPERVISORY PATENT EXAMINER